



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Nashville District Office
297 Plus Park Blvd.
Nashville, TN 37217

April 25, 2000

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

WARNING LETTER-00-NSV-15

FACILITY ID# 117267

William Kail, Administrator
Humboldt General Hospital
3525 Chere Carol
Humboldt, TN 38343

Dear Mr. Kail:

Your facility was inspected on April 13, 2000 by a representative of the State of Tennessee, on contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

Processor QC records were missing for 5 consecutive days for processor 1, [REDACTED] room 1, at site Humboldt General Hospital.

Level 2

Processor QC records were missing 4 out of 21 days of operation in the month 09/1999. This resulted in 19% of the records for processor 1, [REDACTED], room 1.

These specific deficiencies appear on the Post Inspection Report, which was given to your facility at the close of your inspection. These deficiencies are symptomatic of serious problems that could compromise the quality of mammography at your facility and potentially overexpose both patients and employees involved with mammography.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies that the inspection identifies and to promptly initiate permanent corrective actions.

*Original
4/25/00
JEN*

**Humboldt General Hospital
William Kail, Administrator**

If you fail to properly address these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective actions within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125. Any questions in regard to this letter or how to ensure you are meeting MQSA standards, please call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,



Richard D. Debo
Acting Director
New Orleans District Office

HEL/krs

cc: State of Tennessee (Madhavi Reddy)

Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191